AHWP-RAPS Joint Conference – November 11 & 12, 2013, Kuala Lumpur, Malaysia

Telecon Minutes from 26 April, 2013 *(Draft)*

Participants: Dr. Saleah Al Tayyar, PhD; Sherry Keramidas, PhD; Phillippe AuClair, Ali Dalaan, Alfred Kwek, Carol Liu, Lauren Power, Susan Tan, Miang Tanaka, Quan Tran, Rainer Voelksen

Welcome and Introductions – Sherry Keramidas and Saleah Al Tayyar provided an overview and update of the joint planning efforts. Sherry noted the importance of the recent discussions at the IOM meetings regarding the establishment of competencies of the regulatory profession. Additionally, Sherry noted that there is a potential conflict with the IMDRF meeting in November. All group members agreed that efforts to request a date change for the IMDRF meeting would be appropriate. *Action item: The AHWP Secretariat will send a note to IMDRF requesting a date change. Additionally, RAPS will send a similar request.*

Content Planning – Members of the group provided very high-level ideas for what content might be appropriate for the workshop. The following groups were identified as potential target audiences:

- Regulators from global agencies
- Regulatory professionals from industry
- Academia
- HTA professionals
- Healthcare professionals
- Hospital administrators
- Researchers
- Professionals from CROs

The members discussed a variety of topics that might be included in the workshop:

1. **Good Regulatory Practice and the Global Regulatory Framework –** Appropriate for participants from both emerging and established economies. The competency discussion would dovetail nicely into this topic. This session could potentially serve as the opening plenary and provide the context for the additional topics. Current harmonization efforts, the establishment of regulatory frameworks for emerging economies could be addressed here at a high level.
2. **HTA** – Based on the need to discuss this topic with regulators, industry, healthcare professionals and academia. Additionally, potentially to discuss with hospital administrators, clinical research professionals, researchers, based on planning group member comments regarding a perceived lack of understanding. Could the HTA discussion serve to identify and outline the significant differences between HTA for drugs vs. HTA for devices. Again, this was a perceived need from group members.
3. **Medical Device Single Audit Program (MDSAP)** – Stemming from the overview in topic 1 listed above, this topic would delve into the MDSAP program that is a current and active priority for the IMDRF. A working group within the IMDRF is developing a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality

management systems. This is noted as the initial step in creating a single audit program. This could be a timely discussion as the IMDRF is targeting to release 4 final documents on the MDSAP by end of 2013.

4. **Unique Device Identification (UDI)** – Again this is a priority for the IMDRF and they have a working group developing the plan for implementation. Ongoing discussions of alignment and challenges. This is currently a very active area and a revised guidance document is targeted for release in Nov/Dec of 2013.
5. **Building a Regulatory Framework** – Potentially this would be a topic that would appeal to emerging economies, training in good regulatory practice and discussions of capacity building may fit here at a deeper level than topic 1.

Next Steps – Sherry and Lauren will take the comments and suggestions and outline a draft potential agenda and circulate to group members for feedback.